

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A transgenic non-human mammal whose genome comprises an exogenous nucleic acid encoding at least one transgenic polypeptide, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcription control region ranging between about 4.6 kB – 30 kB, wherein said polypeptide is produced in said mammal's saliva at a level of at least 0.5 mg/ml.
2. (Previously Presented) The mammal of Claim 1, wherein said mammal is a monogastric ruminant.
3. (Previously Presented) The mammal of Claim 2, wherein said ruminant is a bovine.
4. (Original) The mammal of Claim 3, wherein said bovine is a cow.
5. (Original) The mammal of Claim 1, wherein said mammal is selected from the group consisting of porcine, ovine, caprine, and equine.
6. (Original) The mammal of Claim 1, wherein said polypeptide comprises an active form.
7. (Original) The mammal of Claim 1, wherein said polypeptide comprises a proactive form.
8. (Original) The mammal of Claim 1, wherein said transgenic polypeptide is human.
9. (Original) The mammal of Claim 1, wherein said transgenic polypeptide is produced at a level of 5.0 mg/ml.
10. (Original) The mammal of Claim 8, wherein said human transgenic polypeptide is selected from the group consisting of phytase, an antibody, a growth hormone, a blood protein, serum albumin, fibrinogen, prothrombin, thrombin and von Willebrand Factor ("vWF").
11. (Original) The mammal of Claim 1, wherein said transgenic polypeptide comprises a specific activity relative to that of the naturally occurring polypeptide.

12. (Original) The mammal of Claim 1, wherein said transgenic polypeptide comprises a specific activity ranging from 25% to 95% relative to that of the naturally occurring peptide.

13. (Original) The mammal of Claim 7, wherein said proactive form is converted into said active form.

14. (Canceled)

15. (Previously Presented) The mammal of Claim 1, wherein said salivary gland-specific expression construct gland cell transgene comprises a parotid gland cell expression construct transgene.

16. (Original) The mammal of Claim 1, wherein said mammal further comprises a flexible tubing inserted into at least one salivary gland pair, wherein said pair comprises a first and second salivary gland.

17. (Original) The mammal of Claim 16, wherein said salivary gland comprises a parotid gland pair.

18. (Original) The mammal of Claim 16, wherein said flexible tubing is inserted into said first salivary gland.

19. (Original) The mammal of Claim 1, wherein said transgenic polypeptide is selected from the group consisting of phytase, an antibody, a growth hormone, a blood protein, serum albumin, fibrinogen, prothrombin, thrombin and von Willebrand Factor ("vWF").

20. (Currently Amended) A method, comprising:

- a) providing;
 - i) a transgenic non-human mammal whose genome comprises an exogenous nucleic acid encoding at least one transgenic polypeptide, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcriptional control region ranging between about 4.6 kB – 30 kB, said mammal capable of producing saliva, wherein said polypeptide is produced in said saliva ~~at a level of at least 0.5 mg/ml~~ and is collected from a salivary gland duct;
 - ii) a flexible tubing to collect said saliva;

- b) making a surgical incision in said salivary gland duct; and
- c) cannulating said duct with said tubing.

21. (Original) The method of Claim 20, further comprising step (d) collecting said saliva in a collection device.

22. (Original) The method of Claim 20, wherein said saliva comprises said polypeptide at 5 mg/ml.

23. (Previously Presented) The method of Claim 21, further comprising the step of isolating said polypeptide from said saliva.

24. (Original) The method of Claim 20, wherein said mammal is a monogastric ruminant.

25. (Previously Presented) The method of Claim 24, wherein said ruminant is a bovine.

26. (Original) The method of Claim 25, wherein said bovine is a cow.

27. (Original) The method of Claim 22, wherein said transgenic polypeptide is human.

28. (Original) The method of Claim 27, wherein said human transgenic polypeptide is selected from the group consisting of phytase, an antibody, a growth hormone, a blood protein, serum albumin, fibrinogen, prothrombin, thrombin and von Willebrand Factor ("vWF").

29. (Previously Presented) A method, comprising:

- a) providing;
 - i) a first DNA sequence comprising 5' cis-acting expression signals, said first DNA sequence being derived from a first salivary gland secretory protein gene, said first gene ranging between about 4.6 kB - 30kB;
 - ii) a second DNA sequence encoding a polypeptide of interest and a region encoding an operable secretion signal, said secretion signal being derived from a second salivary gland secretory protein gene;
 - iii) a third DNA sequence comprising termination and 3' regulatory signals, said third DNA sequence being derived from a third salivary gland secretory protein gene, wherein said first, second,

and third salivary gland secretory protein genes are not necessarily different;

- b) joining said first, second, third DNA sequences in operable linkage effective for salivary gland expression and saliva-specific expression of said polypeptide of interest to create a transgene construct;
- c) cloning said transgene construct to produce a vector;
- d) microinjecting said vector into a non-human mammalian embryo to produce a transgenic non-human mammal whose genome comprises a transgenic polypeptide transgene capable of engendering expression of said polypeptide in saliva of said non-human transgenic mammal, said non-human mammalian embryo is selected from the group consisting of porcine, bovine, ovine, caprine, and equine.

30-31. (Canceled)

32. (Previously Presented) The method of Claim 29, wherein said bovine is a cow.

33. (Original) The method of Claim 29, wherein said transgenic polypeptide is human.

34. (Original) The method of Claim 33, wherein said human transgenic polypeptide is selected from the group consisting of phytase, an antibody, a growth hormone, a blood protein, serum albumin, fibrinogen, prothrombin, thrombin and von Willebrand Factor ("vWF").

35. (Original) The method of Claim 29, wherein said polypeptide is expressed at 5.0 mg/ml.

36-50. (Canceled)

41. (Currently Amended) A transgenic bovine whose genome comprises an exogenous nucleic acid encoding a transgenic prothrombin polypeptide, said nucleic acid operably linked to a proline-rich salivary gland-specific cis-acting 5' transcriptional control element, wherein said control element ranges between about 4.6 – 30 kB, and wherein said prothrombin is produced in said bovine's saliva at a level of at least 0.5 mg/ml.

42. (Previously Presented) The bovine of Claim 41, wherein said bovine is a cow.

43. (Previously Presented) The bovine of Claim 41, wherein said prothrombin is human.

44. (Previously Presented) The bovine of Claim 41, wherein said prothrombin is produced at a level of 5.0 mg/ml.

45. (Previously Presented) The bovine of Claim 41, wherein said transgenic prothrombin comprises a specific activity relative to that of a naturally occurring prothrombin.

46. (Previously Presented) The bovine of Claim 41, wherein said transgenic prothrombin comprises a specific activity ranging from 25% to 95% relative to that of a naturally occurring prothrombin.

47. (Previously Presented) The bovine of Claim 41, wherein said salivary gland-specific expression construct comprises a parotid gland cell expression construct.

48. (Previously Presented) The bovine of Claim 41, further comprising a flexible tubing inserted into at least one salivary gland pair, wherein said pair comprises a first and second salivary gland.

49. (Previously Presented) The mammal of Claim 48, wherein said salivary gland pair comprises a parotid gland pair.

50. (Previously Presented) The mammal of Claim 48, wherein said flexible tubing is inserted into said first salivary gland.

51. (Previously Presented) The method of Claim 29, wherein said genome is derived from a plurality of cells.

52. (Currently Amended) A transgenic non-human mammal whose genome comprises an exogenous nucleic acid encoding at least one transgenic polypeptide, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcription control region ranging between about 4.6 kB – 30 kB, wherein said polypeptide is produced in said mammal's saliva.

53. (Previously Presented) The mammal of Claim 1, wherein said mammal is a monogastric ruminant.

54. (Previously Presented) The mammal of Claim 2, wherein said ruminant is a caprine.

55. (Previously Presented) The mammal of Claim 3, wherein said caprine is a goat.

56. (Previously Presented) The mammal of Claim 1, wherein said mammal is selected from the group consisting of porcine, ovine, bovine, and equine.

57. (New) A transgenic goat comprising a bSP30 promoter, wherein said promoter is operably linked to an exogenous nucleic acid encoding at least one transgenic polypeptide, wherein said polypeptide is produced in said goat's saliva.

58. (New) The transgenic goat of Claim 57, wherein said transgenic polypeptide comprises human serum albumin.

59. (New) The transgenic goat of Claim 57, wherein said bSP30 promoter is a bSP30a promoter.

60. (New) The transgenic goat of Claim 57, wherein said bSP30 promoter is a bSP30b promoter.

61. (New) The transgenic goat of Claim 57, wherein said transgenic polypeptide is a fusion protein.

62. (New) The transgenic goat of Claim 61, wherein said fusion protein comprises human serum albumin and a polypeptide of interest.